

Procter & Gamble

The Procter & Gamble Company
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April 20, 1999

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re.: Docket No. 98N-0970 – "Medical Devices; Labeling
for Menstrual Tampons; Ranges of Absorbency"

Dear Sir or Madam:

This provides 2 copies of comments from The Procter & Gamble Company (P&G) on the above-cited proposed rule, as requested by the notice published in the Federal Register of January 21, 1999 (64 FR 3255).

P&G applauds FDA's initiative in proposing to amend the tampon labeling regulation at 21 CFR 801.430(e)(1) to provide an absorbency term for tampons that absorb 15 to 18 grams of fluid. We agree with FDA's position that the ability of tampon manufacturers to market a tampon of this absorbency range in the U.S. will provide women a means of managing higher menstrual flow without significantly increasing their risk of menstrual Toxic Shock Syndrome (TSS) when using the product in accordance with the prescribed labeling. We appreciate this opportunity to provide our perspective on the proposed rule.

P&G currently manufactures and markets several feminine hygiene products within the United States, including Tampax® unscented menstrual tampons and Always® unscented menstrual pads and pantliners. Based on our experience in the feminine protection business, as well as our extensive history in developing and marketing a broad range of consumer products, we feel it is very important to ensure that the absorbency term used to describe tampons absorbing 15 to 18 grams of fluid is clearly understood by consumers and that it does not lead to confusion or unmet expectations through association with other consumer products.

Part 1 of our comments, below, is focused on P&G's opinion that the FDA-proposed term "ultra" is not suitable to describe tampons that absorb 15 to 18 grams of fluid. Part 1 also provides our proposal for a more suitable alternative absorbency term. In Part 2, we use the opportunity afforded by this proposed rule to provide P&G's position on other aspects of the tampon labeling regulation at 21 CFR 801.430.

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1. "Ultra" is not an appropriate term to describe tampons that absorb 15 to 18 grams of fluid.

FDA proposed that the absorbency term "ultra" be used to describe tampons absorbing fluid in the range of 15 to 18 grams. P&G thinks that the term "ultra" is unsuitable for this application and would be seriously misleading and confusing for consumers. The term "ultra" has a broad history of use with consumer products in the United States, including use with products such as liquid and granular laundry detergents, liquid dishwashing detergents, infant diapers, and menstrual pads. Consumers have learned to understand that the "ultra" designation means that the particular product is more compact, physically smaller, or more concentrated than the "normal" product, but performs as well or better than the larger, bulkier, "full-sized" product.

To the consumer, this has been shown to mean, depending on the product: less weight and bulk to carry home from the supermarket; reduced storage needs in the home; and, in some cases, lower cost because of reduced material and transportation costs. For the environmentally conscious, "ultra" can connote a lower quantity of raw materials per functional unit of product to be consumed and/or disposed of, as well as less packaging material required for a more compact product.

This is clearly not the case for the proposed 15 to 18 gram absorbency category of tampons. In this situation, a dimensionally larger product will be doing a larger job. In other words, a greater quantity of absorbent material will be incorporated into a bigger product which will be capable of absorbing more fluid than tampons currently available in the U.S. Consumers' expectation of a smaller product doing a bigger job will not be met. We are concerned that use of "ultra" to describe this absorbency range will lead to confusion among tampon users and be a source of lack of clarity in the critically important absorbency labeling information on tampon packages.

For menstrual pads and infant diapers, "ultra" was used to designate thinner products. Product performance was maintained by replacing the traditional cellulose absorbent material with synthetic polyacrylate superabsorbent gelling material. Based on these experiences, the consumer could be falsely led to believe that "ultra" tampons contain a similar material.

Recommendation:

P&G proposes the term "**extra plus**" rather than "ultra" to describe tampons capable of absorbing 15 to 18 grams of fluid. "**Extra plus**" is not associated with any pre-existing consumer product uses. Consumer research sponsored by P&G identified "extra plus" as a term understood and preferred by tampon users to describe the absorbency of tampons beyond the current "super plus" category (12 to 15 grams of fluid). In this research, "**extra plus**" did not carry any connotations or associations that would mislead consumers or generate unfulfilled expectations about a tampon in the 15 to 18 gram absorbency range. The term "**extra plus**" is consistent with the

product design based on extra amounts of the same materials used in super and super plus tampons.

P&G strongly recommends that FDA assign the term "**extra plus**" in the table at 21 CFR 801.430(e)(1) to describe tampons capable of absorbing 15 to 18 grams of fluid. This will maintain the clarity of tampon user labeling information, and maximize its utility to women in selecting and using the appropriate absorbency to meet their menstrual needs.

2. P&G supports comments submitted by INDA on this proposed rule for other aspects of "User labeling for menstrual tampons," 21 CFR 801.430.

P&G is a member of INDA, the Association of Nonwoven Fabrics Industry. We have participated, along with several other U.S. tampon manufacturers, in INDA's Feminine Hygiene Task Force to prepare comments on this proposed rule that deal with potential updates and improvements to other aspects of the current "User labeling for menstrual tampons" regulation that appears at 21 CFR 801.430. P&G fully supports and endorses INDA's comments on this proposed rule, including:

- substitution of the term "light" to replace "junior" to designate tampons that absorb six or less grams of fluid [21 CFR 801.430.(e)(1)] to reduce consumer confusion, and
- lowering the TSS incidence statistic in 21 CFR 801.430(d)(2) to reflect the most recent active surveillance of TSS, as cited by Dr. Lillian Yin in her September 13, 1993 letter to tampon manufacturers on "FDA's Position on Eight Hours/Overnight Use of Menstrual Tampons."

In support of these points, P&G encourages FDA to work with its counterparts in other countries (especially Canada and the European Union) to harmonize worldwide tampon labeling regarding TSS. We believe it is important for consumers to see globally consistent TSS labeling information, whether or not this information is mandated by local tampon labeling regulations. The draft "Code of Practices for Tampons" prepared by the European Disposables and Nonwovens Association (EDANA) proposes on-package TSS warning labeling that could serve as the basis for a more universal standard of tampon labeling. We urge FDA to consider this wording to update current 21 CFR 810.430 (c) as the Agency evaluates our proposed modifications to the current "User labeling for menstrual tampons" regulation

Recommendation: In the interest of allowing tampons in the 15 to 18 gram absorbency category to be available to consumers as quickly as possible, P&G suggests that FDA consider issuing a final rule on this aspect of 21 CFR 801.430 alone, and then develop a new proposed rule to generate public comment on the

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additional sections of tampon labeling regulations addressed by INDA's comments and supported by P&G.

Thank you for the opportunity to comment on this proposed rule. We hope our input will help the development of a useful, consumer-understandable absorbency term for this higher absorbency category of tampons, as well as to improve the utility and technical accuracy of the tampon labeling regulation.

Please contact me at (513) 634-5196 if you have any questions about these comments.

Very truly yours,

THE PROCTER & GAMBLE COMPANY

A handwritten signature in black ink, appearing to read "Mark M. Anderson".

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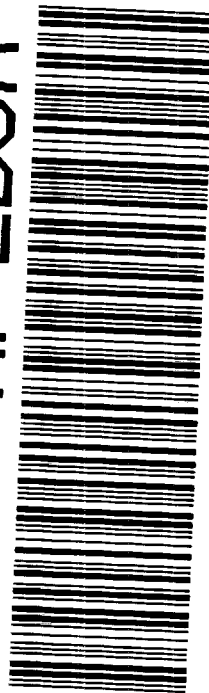
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